rejected as being anticipated by Horstmann *et al.* under 35 U.S.C. § 102(b). The Examiner has contended that Horstmann *et al.* teaches a transdermal system comprising islands containing an active, wherein the islands are obtained by spray drying solutions of active on a moisture-absorbing basic material, citing column 3, lines 10-26 thereof. Scopolamine, a liquid, is specified (citing column 3, line 46), and polymers are disclosed as the basic material (column 3, lines 67-68). This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

The Hortsmann *et al.* patent relates to a transdermal therapeutic system having a layered structure including a matrix layer including a reactive substance, which is activatable, applied to a backing layer, and a separate layer controlling the access of cutaneous liquid. In discussing the efficacy of transdermal applications, as well as the problems associated with same in the background section of this patent, the patentees discuss their object of providing a transdermal therapeutic system which exhibits increased active substance flow and which is stable in storage. This was said to be accomplished by the layered structure of this patent, which includes a matrix 12 (see FIG. 1) containing the active substance and being activatable, as well as a layer 13 controlling the access of cutaneous liquid. Thus, the matrix itself consists of a basic material 15 which is permeable to water vapor, but substantially water insoluble and mainly free of active substance. The basic material comprises islands 14 which are distributed therein, and which consist of a solid pharmaceutical solution and a basic material which is water soluble or water swellable, and in which the matrix is activatable by cutaneous liquid, so that the controlled access of skin moisture into the matrix is effected, and the islands thus absorb moisture so that a system-controlled intended super-

saturation with active substance takes place, resulting in increased pharmaceutical release.

It can therefore be seen that according to these patentees, in order to be effective, the active material is incorporated into the base material of the islands, which is described as

> a variety of pharmaceutical auxiliaries which are swellable in water, such as, e.g., polyvinyl pyrrolidone, polyacrylic acid, polyvinyl alcohol, cellulose and its derivatives, naturally occurring slime formers, e.g., agar (agar), guar gum, and gum arabic, but as well inorganic materials, such as kaolin or bentonite are suitable components...

The polymer compositions of the present invention are entirely different. The overall thrust of the present invention is thus one which permits certain highly plasticizing drugs, such as selegiline, to be used with the adhesive systems thereof for direct application to the skin. This is possible with the adhesives of the present invention, which are different from these pharmaceutical auxiliaries in Horstmann *et al.*, but are not swellable in water. Indeed, they are hydrophobic, as is now specifically required in claim 84. Thus, all of the specific polymers, such as those discussed at page 15, lines 11-24 of the present specification, and in particular the highly useful acrylic-based polymers hereof, are hydrophobic polymers quite unlike those used in the islands 14, 24 of Horstmann *et al.* Indeed, the teachings in Horstmann *et al.* with respect to using hydrophilic, or swellable polymers, would teach one directly away from the hydrophobic polymers of the present invention, and certainly not obviate the present claims.

It is also noted that the system described in Horstmann *et al.* requires water to activate the drug system thereof. They therefore control access of cutaneous liquids such as water by use of the system therein, including layer 13 for moisture access

control. Moisture itself thus improves the activity of the drugs employed by Horstmann *et al.*, and is considered critical to their cutaneous application.

In the present application, on the other hand, only a single layer is necessary, and the matrix-forming agent including the drugs provides for adhesion to the skin itself.

In the December 9, 1999, official action, the Examiner has specifically referred to the disclosure at column 3, lines 10-26 with respect to the process for producing the therapeutic system of Horstmann *et al.* in which the islands are obtained by spray drying a solution of the active substance and the moisture-absorbing basic material in a suitable solvent. Of course, this disclosure does not overcome the above-noted deficiencies in Horstmann *et al.* with respect to the specific materials disclosed therein as constituting the base material for islands 14. The Examiner has also referred to scopolamine as being specified at column 3, line 46. It is noted, however, that at column 3, line 49 selegiline, a preferred composition of the present invention, is specifically disclosed as one of the active substances therein.

As for the Examiner's reference to polymers being disclosed as the basic material at column 3, lines 67-68, it is noted in this regard that the material referred to by the Examiner is the basic material 15 of the matrix 12, and not the base material for the islands 14, which contain the active drug itself, and which are specifically disclosed at column 4, lines 10-16. Again, these are polymers, but they are not the hydrophobic polymers to which the present claims are now specifically directed.

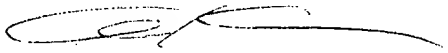
It is therefore now respectfully submitted that all of the claims pending in this application now possess the requisite novelty, utility and unobviousness to warrant their immediate

allowance, and that applicants have clearly overcome Horstmann *et al.* as a legitimate reference hereagainst. Therefore, reconsideration and allowance of these claims is again respectfully solicited. If, however, for any reason the Examiner still does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP



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